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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,353	05/07/2007	Harri Savilahti	0933-0258PUS1	6993

2292 7590 01/11/2010

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EXAMINER	
KETTER, JAMES S	

ART UNIT	PAPER NUMBER
1636	

NOTIFICATION DATE	DELIVERY MODE
01/11/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/553,353	SAVILAHTI ET AL.	
	Examiner	Art Unit	
	James S. Ketter	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *10 and 11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/14/05; 9/29/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election with traverse of Group I, claims 1-9, in the reply filed on 14 September 2009 is acknowledged. The traversal is on the ground(s) that the invention, and thus the special technical feature, is the assembled Mu transposition complex. This is not found persuasive because the reference cited below, Schagen et al., teaches the components of the Mu transposon machinery assembled in the nucleus. The requirement is still deemed proper and is therefore made FINAL. However, the requirement for the species election is hereby WITHDRAWN and all species rejoined for examination on the merits.

Claims 10 and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 14 September 2009.

Claim 5 is objected to because of the following informalities: The claim does not end in a period. Appropriate correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Schagen et al. (of record as reference "CD" on the IDS filed 14 October 2005).

Claim 1 is drawn to a method for incorporating nucleic acid segments into cellular nucleic acid of an isolated eukaryotic target cell, the method comprising the step of: delivering into the eukaryotic target cell an in vitro assembled Mu transposition complex that comprises (i) MuA transposases and (ii) a transposon segment that comprises a pair of Mu end sequences recognised and bound by MuA transposase and an insert sequence between said Mu end sequences, under conditions that allow integration of the transposon segment into the cellular nucleic acid. Claim 3 specifies within claim 1 that the nucleic acid segment is incorporated to a random or almost random position of the cellular nucleic acid of the target cell. Claim 4 specifies within claim 1 that the nucleic acid segment is incorporated to a targeted position of the cellular nucleic acid of the target cell. Claim 5 specifies within claim 1 that the target cell is human, animal, plant, fungi or yeast cell. Claim 7 specifies within claim 1 that said insert sequence comprises a marker, which is selectable in eukaryotic cells. Claim 8 specifies within claim 1 that a concentrated fraction of Mu transposition complexes are delivered into the target cell. Claim 9 specifies within claim 1 that the method further comprises the step of incubating the target cells under conditions that promote transposition into the cellular nucleic acid.

Schagen et al. teaches, e.g., at the abstract, "[W]e cloned the coding sequences of the phage factors MuA and MuB In a eukaryotic expression cassette and fused them to a FLAG epitope and a SV40-derived nuclear localization signal. We demonstrate that these N-terminal extensions were sufficient to target the Mu proteins to the nucleus, while their function in Escherichia coll was not impeded. In vivo transposition in mammalian cells was analysed by co-

transfection of the MuA and MuB expression vectors with a donor construct, which contained a miniMu transposon carrying a Hygromycin-resistance marker (HygR). In all co-transfections, a significant but moderate (up to 2.7-fold) increase in HygR colonies was obtained If compared with control experiments in which the MuA vector was omitted. To study whether the Increased efficiency was the result of bona fide Mu transposition, Integrated vector copies were cloned from 43 monoclonal and one polyclonal cell lines. However, in none of these clones, the junction between the vector and the chromosomal DNA was localized precisely at the border of the Art sites. From our data we conclude that expression of MuA and MuB increases the integration of miniMu vectors in mammalian cells, but that this increase is not the result of bona fide Mu-induced transposition." However, the instant claims do not call for actual transposition, merely the incorporation of the DNA, which Schagen et al. teaches. At pages 3 and 4 of the remarks filed 14 September 2009, Applicants argue that Schagen et al. does not anticipate or teach the claimed invention, as no actual transposition was seen, and that Schagen et al. casts doubt on the ability to produce the active complex in mammalian cells. However, as noted already, the claims do not require that the complex actively cause transposition in the mammalian cells.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schagen et al. (cited above) in view of Zhang (A, newly cited).

Claims 1 and 5 are described above, and are included only because they encompass all of the embodiments of claims 2 and 6, respectively. Claim 2 specifies within claim 1 that said Mu transposition complex is delivered into the target cell by electroporation. Claim 6 specifies within claim 5 that said animal cell is a mouse cell.

Schagen et al. is described above. Schagen et al. differs from the claimed invention in not specifically teaching use of mouse cells as a host and in not teaching electroporation as the method of placing the transposon into said cells. Zhang teaches, e.g., in the Abstract: "The present invention provides transgenic mice and nucleic acid constructs and methods for creating them. The transgenic mice are generated preferably by electroporation-mediated transfection of a nucleic acid construct into the testes of a sterile spermatogenesis-deficient male mouse. The construct includes DNA encoding a spermatogenesis rescue factor resulting in rescue of spermatogenesis while contemporaneously transferring a nucleic acid of interest for expression in the transgenic mouse so that progeny sired by the transgenic mouse also harbor the transgene.

Certain embodiments of the invention also utilize (a) the salmonid derived Sleeping Beauty transposition system to augment genomic integration of the transgene and/or (b) the Cre/loxP recombination system for excision from sired progeny of the DNA responsible for spermatogenesis rescue."

The substitution of one known element (electroporation or mouse cells as a host) for another (calcium phosphate transfection or human cells) would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution of the mouse host cells and electroporation transfection method of Zhang would have yielded predictable results, namely, mammalian cells transfected by a transposon construct. Since actual transposition is not required by the claims, the expectation that the DNA would be placed into the target cells would have been high.

The discussion of Applicants' remarks regarding Schagen et al., set forth above in the previous rejection, are also applied here.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK
7 January 2010

/James S. Ketter/
Primary Examiner, Art Unit 1636